

Application Number 10/781,245
Amendment in response to Office Action mailed June 15, 2009

REMARKS

This Amendment is responsive to the Office Action dated June 15, 2009. Applicant has amended claim 9, and added claims 13-17. Claims 1-17 are pending in the present application upon entry of this Amendment.

Claim Rejection Under 35 U.S.C. § 112

In the Office Action, the Examiner rejected claim 12 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. Claim 12 is not, however, indefinite. Claim 12 specifies that a surface area of the first membrane of claim 11 is smaller than a surface area of the second membrane of claim 11. The Office Action asserted that surface areas lack quantitative indexing to determine what comprises a smaller surface area. Applicant is not sure what exactly is meant by this statement or why it is required to make claim 12 definite. Claim 12 specifies that the first membrane and the second membrane each have a surface area, and that the surface area of the first membrane is smaller than the surface area of the second membrane. Applicant submits that claim 12 particularly points out and distinctly claims the subject matter which applicant regards as the invention, as required by 35 U.S.C. 112, second paragraph.

Claim Rejections Under 35 U.S.C. § 102

In the Office Action, the Examiner rejected claims 9, 11 and 12 under 35 U.S.C. § 102(b) as being anticipated by Kerver (U.S. Patent No. 6,223,081, hereinafter "Kerver"). Applicant respectfully traverses the rejection to the extent such rejection may be considered applicable to the amended claims. Kerver fails to disclose each and every feature of claims 9, 11 and 12, as required by 35 U.S.C. § 102(b), and provides no teaching that would have suggested the desirability of modification to include such features.

Independent claim 9 has been amended to recite an implantable device including a feedthrough assembly disposed within a hermetically sealed housing of the implantable device including means for sensing a physical parameter disposed within a pin and means for hermetically sealing the pin to the housing through an opening in the housing such that at least a portion of the pin extends outside of the housing. Support for this amendment is found throughout Applicant's disclosure including, e.g., at FIG. 13A and paragraph [0069].

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Independent claim 11 recites an implantable device including a feedthrough assembly partially disposed within a hermetically sealed housing of the implantable device. The feedthrough assembly includes a sleeve, an insulator, and a pin. The sleeve is positionable within an opening through a housing of an implantable medical device and hermetically sealable to the housing. The insulator is disposed within the sleeve and hermetically sealed thereto. The pin is disposed within and hermetically sealed to the insulator. The pin includes a hollow, fluid filled interior, a first membrane, and a second membrane. The first membrane is configured to be exposed to an external medium. The second membrane is adapted to be coupled with a sensor positionable within the housing. A physical parameter of the second membrane is sensed by the sensor and correlates to a pressure within the external medium.

In rejecting Applicant's independent claims 9 and 11, the Office Action stated:

Kerver discloses a sleeve comprising bore 31 hermetically sealed using epoxy. The feedthrough is shown in FIG. 1 having an insulator comprising assembly 32 and a pin comprising a hollow, fluid-filled interior with a proximal end 36. The fluid medium within the tube 37 may comprise air, or a suitable gel which transmits the pressure signals.

The pressure sensor element is constructed from two membranes, a first membrane comprising a silicon back plate 65 and a second membrane comprising a silicon diaphragm 68.¹

No other explanation of how or why Kerver discloses each and every element of Applicant's claims is supplied in the Office Action and no other portions of the reference are cited in support thereof. As is clear from the above-reproduced language of Applicant's claims, the Office Action failed to consider numerous elements recited therein (even before the amendments to claim 9 enclosed herein). Applicant also respectfully disagrees with the interpretation of the portions of the reference actually considered in the Office Action. For example, Kerver does not disclose "a sleeve comprising bore 31 hermetically sealed using epoxy," as asserted in the Office Action. Kerver states only that "[t]he lead has a proximal end 36, which is inserted into opening or bore 31 formed in connector housing 33, suitably composed of uncolored, transparent epoxy."² Thus, according to Kerver, the connector housing 33 is composed of uncolored, transparent epoxy. The reference does not disclose that the bore 31 is hermetically sealed to anything, let alone that the bore 31 is a sleeve of a feedthrough assembly

¹ Office Action of June 15, 2009 at p. 4.

² Kerver at column 4, lines 18-21 (emphasis added).

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positionable within an opening through a housing of an implantable medical device and hermetically sealable to the housing, as required by Applicant's claim 11.

Kerver fails to disclose each and every element of Applicant's amended claim 9. In particular, Kerver does not disclose means for hermetically sealing a pin to a housing of an implantable medical device through an opening in the housing such that at least a portion of the pin extends outside of the housing, as required by Applicant's amended claim 9.

Kerver also fails to disclose numerous elements of Applicant's independent claim 11. For example, Kerver fails to disclose a sleeve positionable within an opening through a housing of an implantable medical device and hermetically sealable to the housing, an insulator disposed within the sleeve and hermetically sealed thereto, or a pin disposed within and hermetically sealed to the insulator, all of which are required by claim 11 and none of which appear to have been completely considered in the Office Action. Claim 12 depends from independent claim 11 and is therefore patentable over Kerver for at least the same reasons identified with respect to claim 11.

In order to support an anticipation rejection under 35 U.S.C. § 102(b), it is well established that a prior art reference must disclose each and every element of a claim. This well known rule of law is commonly referred to as the "all-elements rule."³ If a prior art reference fails to disclose any element of a claim, then rejection under 35 U.S.C. § 102(b) is improper.⁴ Kerver fails to disclose each and every limitation set forth in claims 9, 11 and 12. For at least these reasons, the Examiner has failed to establish a *prima facie* case for anticipation of Applicant's claims under 35 U.S.C. § 102(b). Withdrawal of this rejection is requested.

Claim Rejections Under 35 U.S.C. § 103

In the Office Action, the Examiner rejected claims 1-10 under 35 U.S.C. § 103(a) as being unpatentable over Prutchi et al. (U.S. Patent No. 5,556,421, herein after "Prutchi") in view of Karicherla et al. (U.S. Patent No. 7,347,826, hereinafter "Karicherla"). Applicant respectfully traverses the rejection to the extent such rejections may be considered applicable to the claims as

³ See *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 231 USPQ 81 (CAFC 1986) ("it is axiomatic that for prior art to anticipate under 102 it has to meet every element of the claimed invention").

⁴ *Id.* See also *Lewmar Marine, Inc. v. Barent, Inc.* 827 F.2d 744, 3 USPQ2d 1766 (CAFC 1987); *In re Bond*, 910 F.2d 831, 15 USPQ2d 1566 (CAFC 1990); *C.R. Bard, Inc. v. MP Systems, Inc.*, 157 F.3d 1340, 48 USPQ2d 1225 (CAFC 1998); *Oney v. Railiff*, 182 F.3d 893, 51 USPQ2d 1697 (CAFC 1999); *Apple Computer, Inc. v. Articulate Systems, Inc.*, 234 F.3d 14, 57 USPQ2d 1057 (CAFC 2000).

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amended. The applied references fail to disclose or suggest the features defined by Applicant's claims, and provide no teaching that would have suggested the desirability of modification to arrive at the claimed features.

Independent Claim 1

Prutchi in view of Karicherla fails to teach or suggest a feedthrough assembly including a sleeve outer portion hermetically bonded to a hermetically sealed housing of an implantable device, or a pin spaced from the housing and at least partially disposed within a thermal insulator and a temperature sensor disposed within the pin, as required by Applicant's claim 1.

The Office Action interpreted the guide wires 42, 44 disclosed in Karicherla as a pin as recited in Applicant's claim 1. Applicant respectfully disagrees that one of ordinary skill in the art would have read Karicherla and interpreted guide wires 42, 44 as a pin according to that term's ordinary meaning. However, regardless of the propriety of the interpretation of Karicherla proposed by the Office Action, neither Karicherla nor Prutchi teach or suggest that the pin is spaced from the housing or that a temperature sensor is disposed within the pin, as further required by Applicant's claim 1. It does not appear that the Office Action even considered this language of claim 1.

Moreover, neither Prutchi nor Karicherla, alone or in combination teach or suggest a sleeve outer portion (of a feedthrough assembly) that is hermetically bonded to a hermetically sealed housing of an implantable device, as required by Applicant's claim 1. There does not appear to be any discussion or illustration in either of the cited references of this element of Applicant's claim 1, or any equivalent structure that might be modified to comport with this requirement. Again, it does not appear that the Office Action even considered this limitation as claimed by Applicant.

Prima facie obviousness is a procedural tool of examination which allocates who has the burden of producing evidence in each step of the examination process.⁵ The examiner bears the initial burden of factually supporting any *prima facie* conclusion of obviousness.⁶ The applicant is under no obligation to submit evidence of nonobviousness if the examiner does not establish

⁵ Manual of Patent Examining Procedure § 2142 (8th ed. rev. 7, 2008).

⁶ *Id.*

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prima facie obviousness.⁷ To support a rejection under 35 U.S.C. § 103, the reason(s) why the claimed features would have been obvious must be clearly articulated.⁸ The Supreme Court has noted that the analysis supporting an obviousness rejection should be made explicit.⁹ The Federal Circuit has stated that "rejections on obviousness cannot be sustained with mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness."¹⁰ Additionally, "[a]ll words in a claim must be considered in judging the patentability of that claim against the prior art."¹¹

The Office Action failed to establish *prima facie* obviousness, because it did not articulate any rational reason(s) why, having considered all the claimed limitations, the references relied on render claim 1, let alone all of claims 1-8 obvious. The Office Action relied on Prutchi in view of Karicherla to reject Applicant's claims 1-8, but in doing so referred to what appears to be a consolidated characterization of the features embodied in the different claims rejected. Unfortunately, the actual claim language is not considered with respect to any of the references nor does the Office Action explain where or how they teach or suggest the features embodied therein. For example, as noted above, the Office Action completely omitted an explanation of how the cited references teach or suggest a pin that is spaced from the housing or a temperature sensor that is disposed within the pin. In fact, these limitations or any equivalent characterization of these elements from claim 1 does not appear to have been considered at all in rejecting Applicant's claims. Moreover, the Office Action appears not to have considered Applicant's dependent claims 5-8 in the rejection based on Prutchi in view of Karicherla.

Upon consideration of all of the required elements, the cited references, alone or in the manner combined in the Office Action, fail to teach or suggest at least one element of each of claims 1-8 and therefore do not render any of the claims obvious under 35 U.S.C. § 103(a).

⁷ *Id.*

⁸ *Id.*

⁹ *KSR International Co. v. Teleflex Inc.*, 550 U.S. 398, 418, 82 USPQ2d 1385, 1396 (2007).

¹⁰ *In re Kahn*, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006) (emphasis added).

¹¹ M.P.E.P. § 2143.03 (quoting *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970)) (emphasis added).

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Independent Claim 9

As explained above, independent claim 9 has been amended to recite an implantable device including a feedthrough assembly disposed within a hermetically sealed housing of the implantable device including means for sensing a physical parameter disposed within a pin and means for hermetically sealing the pin to the housing through an opening in the housing such that at least a portion of the pin extends outside of the housing. Prutchi in view of Karicherla fails to teach or suggest the features embodied in Applicant's amended claim 9. In particular, the references, alone or in any combination fail to teach or suggest means for hermetically sealing the pin to the housing, wherein the pin extends through an opening in the housing such that at least a portion of the pin extends outside of the housing, as required by Applicant's amended claim 9.

Claims 2-8 depend from claim 1 and are therefore patentable over Prutchi in view of Karicherla for at least the reasons set-out above with reference to claim 1. Similarly, claim 10 depends from claim 9 and is therefore patentable over the cited references for at least the reasons identified above with reference to claim 9. For at least these reasons, the Examiner has failed to establish a *prima facie* case for non-patentability of Applicant's claims 1-10 under 35 U.S.C. § 103(a). Withdrawal of this rejection is requested.

New Claims

Applicant has added claims 13-17 to the pending application. The applied references fail to disclose or suggest the features defined by Applicant's new claims, and provide no teaching that would have suggested the desirability of modification to arrive at the claimed features. As one example, the references fail to disclose or suggest an implantable device including a hermetically sealed housing and a feedthrough assembly disposed in an opening in and hermetically sealed to the housing, the feedthrough assembly comprising a sensor assembly arranged in the opening such that at least a portion of the sensor assembly extends outside of the housing, as recited by claim 13. No new matter has been added by the new claims.

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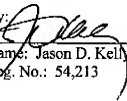
CONCLUSION

All claims in this application are in condition for allowance. Applicant respectfully requests reconsideration and prompt allowance of all pending claims. Please charge any additional fees or credit any overpayment to deposit account number 50-1778. The Examiner is invited to telephone the below-signed attorney to discuss this application.

Date: September 14, 2009

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